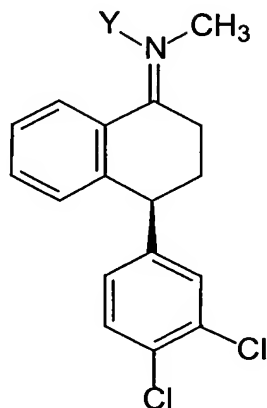


What is claimed is:

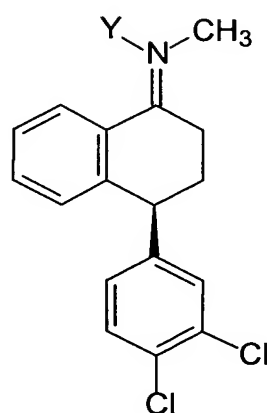
1. A process for preparing sertraline comprising the step of hydrogenating an imine of the formula:



with a cobalt catalyst and converting the hydrogenated compound to sertraline if necessary, wherein Y is optionally an oxygen atom.

2. The process of claim 1, wherein the cobalt catalyst has an oxidation state of  $\text{Co}^0$ .
3. The process of claim 1, wherein the catalyst has a cobalt content of about 10% to about 25% (wt/wt).
4. The process of claim 1, wherein the catalyst has a surface area of about 6 to about 100  $\text{m}^2/\text{g}$ .
5. The process of claim 1, wherein the cobalt is fixed to a support.
6. The process of claim 5, wherein the support is alumina-silica.
7. The process of claim 1, wherein the catalyst has an average pore size of about 100 to about 300 Angstroms.
8. The process of claim 1, wherein Y is not substituted.
9. The process of claim 1, wherein the hydrogenating is carried out in a trickle-bed reactor.
10. The process of claim 9, wherein the hydrogenating is carried out at a temperature of about 80 to about 150°C.
11. The process of claim 9, wherein the hydrogenating is carried out at a pressure of about 5 to about 20 bar.
12. The process of claim 9, wherein hydrogenating is carried out with a hydrogen feed rate of about GHSV 25 to about 5000 per hour.
13. The process of claim 9, wherein the hydrogenating is carried out with feeding a solution of the imine in THF.

14. The process of claim 13, wherein the solution has a concentration of about 10 to about 120 grams/L.
15. The process of claim 9, wherein the hydrogenating is carried out with a weight hourly space velocity of about 5 to about 15 per hour.
16. The process of claim 9, wherein the sertraline prepared has dechlorinated side products of less than about 0.1%.
17. The process of claim 9, wherein the sertraline is prepared with a cis to trans ratio of about 6 to about 14.
18. The process of claim 17, wherein the ratio is about 12.
19. The process of claim 1, wherein the imine is a pure enantiomer.
20. The process of claim 1, further comprising increasing ratio of (+)-cis-sertraline through selective precipitation with mandeleic acid.
21. The process of claim 1, further comprising the step of converting the sertraline to sertraline hydrochloride.
22. A pharmaceutical composition comprising the sertraline hydrochloride of claim 21 and a pharmaceutically acceptable excipient.
23. A process for preparing sertraline from an imine having the formula:

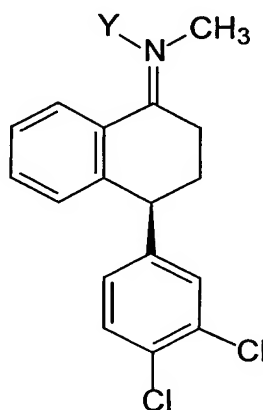


wherein Y is optionally an oxygen atom, comprising the step of hydrogenating the imine with a metal catalyst in a trickle bed reactor and converting the hydrogenated compound to sertraline if necessary.

24. The process of claim 23, wherein the metal is nickel.
25. The process of claim 24, wherein Y is not substituted.
26. The process of claim 24, wherein the catalyst has an oxidation state of zero.
27. The process of claim 24, wherein the catalyst has a nickel content of about 30 to about 80% wt/wt.
28. The process of claim 24, wherein the catalyst has a surface area of about 50 to about 200 m<sup>2</sup>/g.
29. The process of claim 24, wherein the nickel is fixed to an alumina-silica support.
30. The process of claim 24, wherein the hydrogenating is carried out at a temperature of about 65 to about 150°C.
31. The process of claim 30, wherein the temperature is about 90°C.
32. The process of claim 24, wherein the hydrogenating is carried out at a pressure of about 2 to about 15 bar.
33. The process of claim 32, wherein the pressure is of about 8 to about 10 bar.
34. The process of claim 24, wherein the imine is fed as a solution in THF having a concentration of about 10 to about 140 grams/L.
35. The process of claim 24, wherein the hydrogenating is carried out with a weight hourly space velocity of about 40 to about 120 per hour.
36. The process of claim 24, wherein hydrogenating is carried out with a hydrogen feed rate of about GHSV 50 to about 2000 per hour.
37. The process of claim 24, wherein the catalyst has granules selected from the group consisting of about 30 to about 50 mesh and about 50 to about 80 mesh.
38. The process of claim 24, wherein the sertraline has a cis to trans ratio of about 7 to 1.
39. The process of claim 24, wherein the hydrogenating results in dechlorinated side products of about 0.1%.
40. The process of claim 24, further comprising increasing ratio of (+)-cis-sertraline through selective precipitation with mandelic acid.
41. The process of claim 24, further comprising the step of converting the sertraline to sertraline

hydrochloride.

42. A pharmaceutical composition comprising the sertraline hydrochloride of claim 41 and a pharmaceutically acceptable excipient.
43. A process for preparing sertraline from an imine having the formula:



wherein Y is optionally substituted with an oxygen atom, comprising the step of hydrogenating the imine with a nickel containing catalyst having fixed support in a batch reactor and converting the hydrogenated compound to sertraline if necessary.

44. The process of claim 43, wherein Y is not substituted.
45. The process of claim 43, wherein the catalyst has an oxidation state of zero.
46. The process of claim 43, wherein the catalyst has a nickel content of about 30 to about 80% wt/wt.
47. The process of claim 43, wherein the catalyst has a surface area of about 50 to about 200 m<sup>2</sup>/g.
48. The process of claim 43, wherein the nickel is fixed to an alumina-silica support.
49. The process of claim 43, wherein hydrogenating is carried out at a temperature of about 65°C to about 150°C.
50. The process of claim 49, wherein the temperature is of about 120 to about 150°C.
51. The process of claim 43, wherein hydrogenating is carried out at a pressure of about 5 to about 8 bar.
52. The process of claim 51, wherein the pressure is about 8 bar.
53. The process of claim 43, wherein the imine is loaded into the reactor at about 30g to about 125g per liter of solvent.

54. The process of claim 43, wherein the hydrogenating is carried out in a solvent selected from the group consisting of methanol, ethanol, toluene, ethyl acetate, 1,4-dioxane and THF.
55. The process of claim 54, wherein the solvent is THF.
56. The process of claim 54, wherein the solvent is dioxane.
57. The process of claim 43, wherein a cis/trans ratio of about 7 to about 1 is obtained.
58. The process of claim 43, wherein the sertraline obtained has a DCS-compounds of less than about 0.2%.
59. The process of claim 43, further comprising the step of converting the sertraline to sertraline hydrochloride.
60. A pharmaceutical composition comprising the sertraline hydrochloride of claim 43 and a pharmaceutically acceptable excipient.
61. A process for preparing sertraline from sertraline-1-imine comprising the step of reducing sertraline-1-imine in a batch reactor with a Ni/Kieselguhr catalyst.
62. The process of claim 61, wherein a ZnO<sub>2</sub> promoter is used with the catalyst.
63. A process for preparing sertraline from sertraline-1-imine comprising the step of hydrogenating sertraline-1-imine in the presence of a catalyst in a trickle bed reactor.
64. The process of claim 63, wherein a cobalt catalyst is used for hydrogenation.
65. A pharmaceutical composition comprising the sertraline or a hydrochloride salt of claim 64 and a pharmaceutically acceptable excipient.
66. A process for preparing sertraline comprising the steps of:
- a) providing a cobalt containing catalyst made up of cobalt oxide fixed on an alumina-silica support;
  - b) loading the catalyst in a trickle bed reactor;
  - c) reducing the cobalt oxide catalyst;
  - d) feeding the reactor with hydrogen and a solution of sertraline 1-imine in THF;
  - e) recovering the sertraline;
  - f) optionally repeating steps (d) and (e) with a preliminary step of removing any tar on the catalyst; and
  - g) optionally converting the sertraline to sertraline hydrochloride.
67. The process of claim 66, wherein reducing is carried out with a stream of hydrogen at GHSV

(gas hour space velocity)  $2500\text{h}^{-1}$ .

68. The process of claim 67, wherein temperature during reducing is increased to at least about  $450^{\circ}\text{C}$ , at interval of about  $3\text{--}8^{\circ}\text{C}/\text{min}$ , and maintained constant for at least about 2 hours.
69. A process for preparing sertraline comprising hydrogenating sertraline-1-imine with a cobalt catalyst in a trickle-bed reactor fed with sertraline imine solution in THF of  $30\text{g imine/L}$  at weight hourly space velocity of about  $12.5\text{h}^{-1}$ , a pressure of about 8 bar and a temperature of about  $120^{\circ}\text{C}$ .
70. A pharmaceutical composition comprising the sertraline or a hydrochloride salt of claim 69 and a pharmaceutically acceptable excipient.
71. A process for preparing sertraline comprising hydrogenating sertraline-1-imine in solution in THF having a concentration in the range of about 10 to about  $140\text{ g/L}$  with a nickel catalyst fixed on a support in a trickle-bed reactor, at a temperature of about  $65$  to about  $150^{\circ}\text{C}$ , a pressure of about 2 to about 15 bar, a WHSV of about 40 to about 120 per hour, and a hydrogen feeding range of GHSV about 50 to about 2000 per hour.
72. The process of claim 71, wherein the temperature is about  $90^{\circ}\text{C}$ , the pressure about 8 to about 10, the concentration of the imine solution at about  $30\text{ g/L}$ , and the WHSV at about 85 per hour.
73. A pharmaceutical composition comprising the sertraline or a hydrochloride salt of claim 71 and a pharmaceutically acceptable excipient.
74. A process for preparing sertraline comprising hydrogenating with a nickel catalyst fixed on a support in a batch reactor sertraline-1-imine in solution in THF having a concentration in the range of about 30 to about  $125\text{ g/L}$ , pressure of about 5 to about 8 bar, temperature range of about  $65$  to about  $150^{\circ}\text{C}$ .
75. The process of claim 74, wherein the pressure is about 8 bar and the temperature about 120 to about  $150^{\circ}\text{C}$ .
76. Sertraline or a hydrochloride salt thereof in solid state comprising less than about 0.1% of the dechlorinated side products as area percentage HPLC according to U.S. Pharmacopoeia.
77. The sertraline of claim 76, wherein the dechlorinated compounds are about 0.05%.
78. A pharmaceutical composition comprising of sertraline hydrochloride of claim 76, and a pharmaceutically acceptable excipient.
79. A process for preparing a cobalt catalyst suitable for reduction of sertraline-1-imine comprising

the steps of:

- a) calcining an alumina-silica support;
  - b) evaporating moisture from the calcined support;
  - c) contacting the calcined support with an aqueous solution of cobalt nitrate to saturate the surface of the support to obtain a catalyst;
  - d) drying the catalyst; and
  - e) calcining the catalyst in the presence of hydrogen to obtain an oxidation state of CoO.
80. The process of claim 79, wherein the calcining is carried out by heating to a temperature of at least about 450°C.
81. The process of claim 80, wherein the temperature is about 500°C.
82. The process of claim 79, wherein evaporating is carried out under reduced pressure.
83. The process of claim 79, wherein the drying is carried out of about 100°C to about 140°C.
84. The process of claim 83, wherein the temperature is about 120°C.
85. The process of claim 79, wherein the hydrogen is added to a reactor at a rate of about GHSV 2000h<sup>-1</sup> to about 3000h<sup>-1</sup>.
86. The process of claim 85, wherein the hydrogen is added at a rate of about GHSV 2500 per hour.
87. The catalyst prepared by the process of claim 79.